

Caution:

This consultation draft is intended to facilitate dialogue concerning its contents. Should the decision be made to proceed with the proposal, the comments received during consultation will be considered during the final preparation of the regulation. The content, structure, form and wording of the consultation draft are subject to change as a result of the consultation process and as a result of review, editing and correction by the Office of Legislative Counsel.

CONSULTATION DRAFT

[Bilingual]

ONTARIO REGULATION

to be made under the

HEALTH SECTOR PAYMENT TRANSPARENCY ACT, 2017

GENERAL

Recipients

1. The following persons and entities are prescribed as recipients for the purposes of the Act:

1. A person who is a member of a College within the meaning of the *Regulated Health Professions Act, 1991*.
2. A professional corporation incorporated or continued under the *Business Corporations Act* that holds a valid certificate of authorization issued under the *Regulated Health Professions Act, 1991*.
3. A person or entity that operates a hospital within the meaning of the *Public Hospitals Act* or a private hospital within the meaning of the *Private Hospitals Act*.
4. The University of Ottawa Heart Institute/Institut de cardiologie de l'Université d'Ottawa.
5. A person or entity that operates a psychiatric facility within the meaning of the *Mental Health Act* except if the facility is,
 - i. a correctional institution operated or maintained by a member of the Executive Council, other than the Minister of Health and Long-Term Care, or
 - ii. a prison or penitentiary operated or maintained by the Government of Canada.

6. A licensee within the meaning of the *Long-Term Care Homes Act, 2007*.
7. A service provider within the meaning of clauses (b), (c) and (d) of the definition of that term in subsection 2 (1) the *Home Care and Community Services Act, 1994*.
8. A not-for-profit corporation without share capital incorporated under Part III of the *Corporations Act* that operates a community health centre.
9. A not-for-profit entity that provides community mental health and addiction services.
10. A not-for-profit entity that operates a family health team.
11. A not-for-profit entity that operates a nurse-practitioner-led clinic.
12. A not-for-profit entity that operates an Aboriginal health access centre.
13. A person or entity that provides primary care nursing services, maternal care or inter-professional primary care programs and services.
14. A not-for-profit entity that provides palliative care services, including a hospice.
15. A person or entity that provides physiotherapy services in a clinic setting that is not otherwise prescribed under this section.
16. An independent health facility within the meaning of the *Independent Health Facilities Act*.
17. A community health facility within the meaning of the *Oversight of Health Facilities and Devices Act, 2017*.
18. The holder of a certificate of accreditation for the operation of a pharmacy under section 139 of the *Drug and Pharmacies Regulation Act*.
19. An owner or operator of a laboratory or specimen collection centre within the meaning of the *Laboratory and Specimen Collection Centre Licensing Act*.
20. A College within the meaning of the *Regulated Health Professions Act, 1991*.
21. An association that advocates for the interests of health care professionals, health care organizations, or a sector within the health care system.
22. An advocacy group that has a mandate related to a particular disease, disorder or disability,

- i. to combat the disease, disorder or disability,
 - ii. to provide support to individuals or to their families or caregivers, or
 - iii. to advocate for improving or protecting the health of an individual or of their families or caregivers.
23. A foundation or other charitable corporation that is established to raise funds for the purpose of providing grants or other financial support to one or more persons or entities prescribed under this section.
24. A group purchasing organization, shared service organization, or other corporation controlled by one or more persons or entities prescribed under this section that exists solely or primarily for the purpose of purchasing goods or services for the persons or entities.
25. A university in Ontario or a college of applied arts and technology and post-secondary institution in Ontario whether or not affiliated with a university.
26. A person who is fulfilling the requirements to become a member of a health profession as set out in Schedule 1 to the *Regulated Health Professions Act, 1991*.
27. A not-for-profit research institute or organization that conducts research intended to support the development of knowledge related to human health or health care.
28. A subsidiary, within the meaning of the *Business Corporations Act*, of a person or entity prescribed under this section that is incorporated.
29. An individual who is employed, contracted or otherwise retained by a person or entity prescribed under this section to conduct research.
30. An individual who is a board member, director, trustee, officer, appointee, employee, or agent of a person or entity prescribed under this section.
31. An immediate family member of an individual prescribed under this section, except where the transfer of value is provided to the family member for reasons unrelated to the individual's role in the health care system. For this purpose, without restricting the ordinary meaning of the term, an "immediate family member" includes a spouse, parent, child, sibling, grandparent, grandchild, stepparent, stepchild, stepbrother, stepsister, father-in-law, mother-in-law, daughter-in-law, son-in-law, brother-in-law, or sister-in-law.

Transfer of value

2. (1) Without limiting the generality of the definition set out in section 2 of the Act, and subject to subsection (2) of this section,

“transfer of value” includes,

- (a) cash or cash equivalents;
- (b) in-kind items or services;
- (c) security, security option, or any other ownership or investment interest;
- (d) compensation for services, including consulting fees or speakers fees;
- (e) honoraria;
- (f) grants and donations;
- (g) event sponsorships;
- (h) membership fees;
- (i) rental or facility fees;
- (j) rebates and discounts;
- (k) items that are provided on a value-added basis in connection with a procurement;
- (l) supplies and equipment, including information technology;
- (m) leases or other arrangements for the use of supplies and equipment lasting more than 90 days;
- (n) licences and copyright fees including, but not limited to, software licences and article re-prints;
- (o) renovations or leasehold improvements;
- (p) entertainment, social and sporting events;
- (q) food and beverages;
- (r) travel and accommodation;

- (s) personal gifts;
- (t) royalties;
- (u) referral fees;
- (v) payments to cover marketing and advertising costs;
- (w) inventory listing or stocking fees; and
- (x) charitable contributions made in the name of a recipient within the meaning of the Act.

(2) Transfer of value does not include the fair market value of goods that are sold by a payor to a recipient for consideration under a bill of sale or purchase agreement.

Drug

3. A substance described in clause (f.1) of the definition of “drug” in subsection 1 (1) of the *Drug and Pharmacies Regulation Act* is excluded from the definition of “drug” for the purposes of the *Health Sector Payment Transparency Act, 2017*.

Intermediary

4. (1) For the purpose of the definition of “intermediary” in section 2 of the Act, a person or entity is deemed to be providing or facilitating a transfer of value on behalf of a payor if the transfer of value originates from a payor, whether or not the payor,

- (a) directs how the transfer of value is to be used by the intermediary; or
- (b) is aware of the identities of the recipients at the time the transfer of value is provided to the intermediary.

(2) Despite subsection (1), a person or entity that directly or indirectly receives a transfer of value that originates from a payor and provides it directly or indirectly to a recipient is not an intermediary if,

- (a) the person or entity is prescribed under section 1 of this Regulation;
- (b) the payor does not direct how the transfer of value will be used by the person or entity referred to in clause (a); and
- (c) a published ethical guideline, code of ethics or accreditation standard that is commonly accepted within the applicable field would be breached,

- (i) by the person or entity referred to in clause (a) if they disclosed the identity of the recipient to the payor, or
- (ii) by the payor if the payor were to find out the identity of the recipient.

Additional payors

5. The following persons and entities are prescribed as payors for the purposes of paragraph 6 of section 3 of the Act:

1. The holder of a certificate of accreditation for the operation of a pharmacy under section 139 of the *Drug and Pharmacies Regulation Act*.
2. The owner or operator of a laboratory or specimen collection centre within the meaning of the *Laboratory and Specimen Collection Centre Licensing Act*.

Exceptions to reporting requirement

6. For the purposes of section 4 of the Act, a payor is not required to report the following transactions:

1. Transactions that have a dollar value of less than \$10.
2. Salary and benefits that are provided by a payor to a recipient who is employed by the payor under a contract of service.
3. Medical products that are provided to a recipient that are intended to be given to patients by the recipient free of charge.
4. Educational materials and items that are provided to a recipient and are intended to be used by the recipient in a clinical setting for the benefit of patients, such as anatomical models and wall charts.
5. Compensation provided to a recipient to provide expert testimony or other services with respect to a legal proceeding.
6. Benefits that are provided by a drug manufacturer in accordance with ordinary commercial terms that meets all of the conditions set out under subsection 1 (11) of Ontario Regulation 201/96 (General) made under the *Ontario Drug Benefit Act*.

Information re parties to transactions

7. (1) For the purposes of subparagraph 1 i of subsection 4 (5) of the Act, the legal and operating names of a business include,

- (a) the business name of the business, and its business identification number; and

- (b) the legal name of a business that is a corporation, and its Ontario or Canadian corporate number.

(2) For the purposes of subparagraph 1 ii of subsection 4 (5) of the Act, all of the following that apply to an individual are prescribed as identifying information for the individual:

1. The full legal name of the individual.
2. The individual's designation as a health care professional, the name of the regulated health College to which the individual belongs, the individual's licence number and the individual's title.
3. The individual's designation as any other professional and the name of licensing body of the individual's profession.
4. The name of the individual's employer and the individual's job title.

(3) For the purposes of paragraph 5 of subsection 4 (5) of the Act, where the transfer of value is a good or a service, its dollar value includes any taxes that are paid in respect of that good or service.

(4) For the purposes of paragraph 7 of subsection 4 (5) of the Act, the following information is prescribed for each business that is a party to a transaction:

1. An individual who is the administrative contact for the business.
2. The full legal name of the individual and individual's job title, e-mail address and phone number.

(5) Where a transfer of value is made through one or more intermediaries, the payor shall report that fact to the Minister, together with all the information respecting the intermediary or intermediaries that would apply under this section with respect to a party to a transaction.

Transfer of value, description

8. (1) In describing the transfer of value under paragraph 6 of subsection 4 (5) of the Act, the payor must describe the transfer of value as taking one of the following forms:

1. Cash or cash equivalent.
2. In-kind items or services.
3. Security, security option, or any other ownership or investment interest.

(2) The payor must further categorize the transfer of value as belonging to one of the following categories, and where indicated, subcategories:

1. Charitable donations, with the following subcategories:
 - i. To a recipient.
 - ii. On behalf of a recipient.
2. Grants, with the following subcategories:
 - i. Event sponsorship.
 - ii. Space rental or facility fees.
 - iii. Public awareness campaign.
3. Food and beverage.
4. Fees for service as speaker, with the following subcategories:
 - i. Speaking fees – Educational program.
 - ii. Speaking fees – Conference or other gathering.
5. Fees for professional services and consulting, with the following subcategories:
 - i. Consulting fees.
 - ii. Honoraria.
 - iii. Referral fees.
6. Gift and entertainment, with the following subcategories:
 - i. Personal gift.
 - ii. Entertainment.
 - iii. Social event.
 - iv. Sporting event.
7. Travel and accommodation, with the following subcategories:

- i. International.
 - ii. National.
 - iii. Provincial.
8. Education, with the following subcategories:
 - i. Patient — Article, re-print, or other educational item.
 - ii. Recipient — Article, re-print, or other educational item.
 - iii. Sponsor — Accredited continuing education.
 - iv. Sponsor — Unaccredited education or continuing education.
 - v. Recipient — Supervision and training.
 - vi. Recipient — Accredited continuing education, including registration fees.
 - vii. Recipient — Unaccredited education or continuing education, including registration fees.
9. Royalties, memberships and subscriptions, with the following subcategories:
 - i. Royalties paid to a recipient in respect of intellectual property.
 - ii. Royalties paid on behalf of a recipient in respect of intellectual property.
 - iii. Membership fees paid on behalf of a recipient.
 - iv. Subscription fees paid on behalf of a recipient.
10. Current or prospective ownership or investment interest.
11. Research, with the following subcategories:
 - i. Clinical trial.
 - ii. Research agreement.
 - iii. Research grant.

12. Rebates, discounts and items that are provided on a value added basis in connection with a procurement, with the following subcategories:
 - i. Rebates.
 - ii. Discounts.
 - iii. Other value adds.
13. Operational support, with the following subcategories:
 - i. Supplies and equipment, including information technology.
 - ii. Renovations or leasehold improvements.
 - iii. Inventory listing or stocking fees.
 - iv. Medical activity fee paid or provided to a clinic at which a recipient practices.
 - v. Loan of medical device.
14. Marketing and advertising.
15. Partnering agreements with organizations.

(3) A payor may include with the description a contextual statement of no more than 250 characters to indicate the reason for the transfer of value.

Record retention

9. (1) A payor, intermediary or recipient that is a party to a transaction described in subsection 4 (1) of the Act shall retain any records that the party creates or receives with respect to the transaction for at least seven years from the date of the transaction.

(2) For the purpose of this section,

“records” includes any records related to the corrections process set out under section 12 of this Regulation.

Manner and frequency of reporting

10. (1) Every payor shall report to the Minister, no later than June 30 in any year after 2019, all transfers of value from the previous calendar year.

(2) The payor shall report all transfers of value through an electronic data collection platform created and maintained by the Minister.

Where intermediary to be treated as recipient, conditions

- 11.** (1) A market research firm is deemed to be a recipient, and not an intermediary, where,
- (a) a manufacturer gives a payment or other transfer of value to the market research firm which the firm uses to offer incentives to recipients to encourage their participation in a market research study relating to a medical product;
 - (b) the manufacturer does not know the identity of the recipients; and
 - (c) knowing the identity of the recipients would place the manufacturer in breach of an obligation set out within a published ethical guideline or code of ethics that is commonly accepted within the industry.
- (2) Where the circumstances described in subsection (1) exist,
- (a) the payor shall report to the Minister the information required under subsection 4 (5) of the Act in respect of the portion of the payment it makes to the market research firm for use as incentives; and
 - (b) the payor is not required to report on the amounts paid to the market research firm as consideration for their services.
- (3) In this section,

“market research firm” means a company that is retained by a payor to conduct market research relating to a medical product; (cabinet d’études de marché)

“manufacturer” means a payor described in paragraph 1 of section 3 of the Act. (fabricant)

Corrections

12. (1) For the purposes of section 7 of the Act, the following are prescribed as persons who may request that the Minister correct the information reported under the Act, as long as they have complied with the applicable requirements under this section:

- 1. A payor.
 - 2. A recipient.
 - 3. An intermediary or affiliate who is required to report to the Minister under subsection 4 (3) of the Act.
- (2) A payor shall, no later than March 31 in any year after 2019,

- (a) notify each recipient in writing of the information it intends to report to the Minister relating to each transfer of value it provided to the recipient during the previous calendar year; and
- (b) ensure that the recipient has a minimum of 45 days to review the information before it is reported to the Minister.

(3) A recipient seeking to have information corrected shall,

- (a) advise the payor of the information that the recipient believes to be incorrect;
- (b) provide the payor with corrected information along with substantiating materials, if any; and
- (c) request that the payor amend the information.

(4) A payor shall, within 30 days of the receipt of a correction request submitted by a recipient in accordance with subsection (3), review the information provided by the recipient and notify the recipient in writing of the payor's decision with respect to the request, including reasons for the decision.

(5) If a payor agrees with a recipient that the information should be corrected, the payor shall submit the corrected information to the Minister within 15 days of providing notice of its decision under subsection (4), and shall copy the recipient on that request.

(6) If a payor does not agree with a recipient and does not believe that the information should be corrected, the payor shall, within 15 days of providing notice of its decision under subsection (4), submit to the Minister a written request to mark the information as disputed and shall copy the recipient on that request.

(7) A payor may, at any time, request a correction in respect of information that it has already reported to the Minister, as long as the payor has given prior written notice and particulars to the affected recipients.

(8) No intermediary or affiliate shall request a correction to information it has reported to the Minister under subsection 4 (3) of the Act without giving prior written notice and particulars to affected recipients.

(9) Despite anything else in this Regulation, no request for correction or request to mark information as disputed may be submitted to the Minister later than 12 months after the date on which the Minister first publishes the information.

Service of compliance orders

13. (1) For the purposes of subsection 11 (5) of the Act, a compliance order may be served,

- (a) by personal service;
- (b) by sending it by registered mail addressed to the person or entity to be served at their last known address;
- (c) by sending it by fax to the person or entity to be served at their last known fax number; or
- (d) by sending it by commercial courier to the person or entity to be served at their last known address.

(2) Where a compliance order is served in a manner described in subsection (1), the person or entity shall be deemed to have received the notice,

- (a) in the case of an order sent by registered mail, on the fifth business day after the day it was mailed;
- (b) in the case of an order sent by personal delivery or fax, on the first business day after the day it was sent; or
- (c) in the case of an order sent by commercial courier, on the second business day after the commercial courier received the document.

[Commencement]

14. [Commencement]